DEPARTMI **8320-01**

38 CFR Part 17

RIN 2900-AQ65

Transplant Procedures with Live Donors and Related Care and Services

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final, with changes, a proposed rule amending its medical regulations to implement legislation providing it stand-alone authority to provide procedures to remove a solid organ or bone marrow from a live donor for transplantation into a veteran and to furnish the live donor care or services before and after the procedure required in connection with the veteran's transplantation procedure. This rulemaking implements the mandates of section 153 of the VA MISSION Act of 2018.

DATES: This rule is effective [insert date 30 days after date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Mani Murugavel, DNP, NE-BC, CSSGB, RN, National Director, Clinical Services, National Surgery Office (11SURG), Veterans Health Administration, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 461-7130. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: In a document published in the Federal Register (FR) on March 24, 2021, (86 FR 15628), VA proposed to amend its medical regulations to implement its authority to provide procedures to remove a solid organ or bone marrow from a live donor for transplantation into a veteran and to furnish the live donor care or services before and after the procedure. VA provided a 60-day comment period, which ended on May 24, 2021. Six comments were received.

Comments

The six comments were generally supportive of the proposed rule, and we thank the commenters for their comments. Of those six comments, four included substantive feedback, which is discussed below.

One commenter opined that live donors should be further compensated. This commenter suggested VA cover additional expenses that are deemed necessary and for which live donors submit documentation, as there are "other factors such as emotional effects that donors sometime[s] experience" due to the transplant procedure. However, this commenter did not specify the types of additional expenses VA should cover.

As explained in the proposed rule, VA will cover for the live donor hospital care and medical services prior to the surgical removal of the solid organ, part of a solid organ, or bone marrow; the surgical procedure to remove a solid organ, part of a solid organ, or bone marrow, and related care; and follow-up care which varies based on the type of donation. Additionally, VA will cover travel costs, including temporary lodging as VA determines to be needed. While VA acknowledges that live donors may incur additional expenses, VA believes the services and expenses covered under this rulemaking are reasonable under section 1788 of title 38, United States (U.S.C.), are consistent with how VA has administered the transplant program to date, and recognize the sacrifices that live donors make. While VA understands the commenter's support and rationale for expanding upon the additional expenses covered by VA, VA is not making any changes based on this comment.

To the extent that this commenter further suggested that live donors should be compensated for their donation, by law, VA may not knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. 42 U.S.C. 274e(a). For purposes of this statute, the term "valuable consideration" "does not include the

reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ." Section 274e(c)(2). Although this prohibition does not apply to a "human organ paired donation," (see last sentence of section 274e(a)), that is not to say that compensation is available in these cases, because the term "human organ paired donation," as defined in section 274e(c)(4), clearly bars valuable consideration from being provided for the organ in subparagraph (c)(4)(F). Thus, furnishing compensation for a human organ is legally barred. In addition, a host of ethical questions are raised by such a proposal. Transplant programs participating in the Organ Procurement Transplantation Network (OPTN) are authorized, however, to provide reimbursement for incidental non-medical expenses of donors. See 42 U.S.C. 274f, as implemented by § 121.14 of title 42, Code of Federal Regulations (CFR). This authority is discretionary, and while VA voluntarily participates and complies with OPTN requirements and is an OPTN-designated transplant program, VA will cover only the non-medical costs we have identified, as these types of non-medical costs are directly integral to the donor's transplant episode. In addition, this aligns with how very limited non-medical care benefits, or financial incentives, exist for other VA beneficiaries. Nonetheless, VA will undertake additional review and analysis to determine whether non-medical expenses other than those already covered under this rulemaking should be covered to encourage greater donor participation. If VA determines additional non-medical expenses such as incidental non-medical costs described in 42 CFR 121.14 should also be covered, it will propose to do so in a separate future rulemaking.

VA therefore makes no changes based on this comment.

Another commenter stated that it was unclear whether the definition of kidney paired donation, in 38 CFR 17.395(b), included living donor chains, and suggested VA

modify this definition to explicitly cover living donor chains. As explained in OPTN policies, a living (or live) donor chain is an approach in which a live donor without an intended recipient donates an organ, which is matched with a recipient. See OPTN, Policy 1: Administrations Rules and Definitions, and Policy 13: Kidney Paired Donation. U.S. Department of Health and Human Services, Health Resources and Services Administration. Retrieved from: *https:// www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/optn_policies.pdf* (Accessed: 25 October 2021). That recipient's prospective live donor then donates an organ that can be matched with another recipient. Id. A chain of donations then occurs that allows for the donation and receipt of compatible organs. Id. Currently, live donor chains are widely used for the donation and receipt of kidneys.

The definition of kidney paired donation in § 17.395(b) is consistent with OPTN's definition of kidney paired donation. However, it does not specifically address live donor chains nor does it prohibit live donor chains. For the purposes of this rulemaking, VA clarifies that live donor chains are permitted, and interpreted to be included, under VA's definition of kidney paired donation. Based on this comment, VA is adding a note to the definition of kidney paired donation to state that for purposes of this section, kidney paired donation includes live donor chains. VA is also adding a definition for live donor chain to mean a set of kidney paired donation matches that begins with a donation of a kidney from a live donor without an intended recipient. Such live donor donates a kidney for transplantation into the intended recipient of a prospective live donor. The prospective live donor then donates a kidney for transplantation into a recipient other than the intended recipient. A chain continues to allow donation and receipt of compatible kidneys. VA makes no further changes based on this comment.

One commenter suggested that VA revise its rule to specify that VA bone marrow programs follow standards of care and patient safety issued by the nation's bone

marrow registry, as they opined that it is critical VA and non-VA bone marrow programs align. This commenter noted that National Marrow Donor Program (NMDP) network members are held to standards of care and safety for bone marrow transplant similar to OPTN members.

As an initial matter, NMDP manages a bone marrow registry in which donors unrelated to the transplant recipient can voluntarily register to donate their bone marrow (including stem cells). These donations are then stored and managed by NMDP. While medical hospitals and facilities can become NMDP-contracted bone marrow donor centers, which are subject to NMDP Donor Center participation standards, VA does not have any such bone marrow donor centers as part of its bone marrow transplantation program. Instead, VA contracts with NMDP to obtain bone marrow for transplantation when a bone marrow match is identified (through NMDP's registry) for a veteran recipient. VA also may obtain bone marrow directly from live donors who are identified by VA as a match for the veteran recipient.

To the extent that this commenter is suggesting VA revise the rule to specify that VA's bone marrow program follows standards of care and patient safety issued by NMDP for live donors of bone marrow, NMDP maintains standards for bone marrow donor centers, specifically related to the bone marrow donor. Because VA does not operate NMDP-contracted bone marrow donor centers, related NMDP standards do not apply to VA. When VA procures bone marrow including stem cells from NMDP for transplantation into a veteran recipient, VA does not directly interact with the bone marrow donor and thus any standards about donor care would be inapplicable, particularly as VA would not know the identity of the live donor. Therefore, NDMP donor center participation standards do not apply to VA's bone marrow transplantation program because VA does not operate such donor centers. As noted earlier, VA may obtain bone marrow directly from live donors (for example, family members of the

veteran) who are identified by VA as a match for the veteran recipient; however, such donations do not fall under NMDP standards for donor centers. VA believes the current language in the regulation regarding care for bone marrow donors is sufficient, particularly as it is consistent with VA current policy and practices. VA does not make any changes to the regulation based on this comment.

NMDP also maintains standards, including data reporting, relating to the unrelated allogeneic bone marrow transplant procedure. VA voluntarily complies with such standards. To the extent that this commenter is suggesting VA revise the rule to specify that VA's bone marrow program follows standards of care and patient safety issued by NMDP for transplant recipients, VA considers this outside the scope of the rulemaking as this relates to transplant recipients, not live donors. VA makes no changes to the regulation based on this comment.

That same commenter also suggested the rule be revised to specify that data reporting requirements for bone marrow transplant be submitted to the Stem Cell Therapeutic Outcomes Database (SCTOD), as that "database allows analysis of program use, center-specific outcomes, size of donor registry and cord blood inventory, and patient access to hematopoietic cell transplantations, and per the Stem Cell Therapeutic and Research Act of 2005, VA would share outcomes data with the SCTOD."

VA voluntarily complies with the Foundation for the Accreditation of Cellular Therapy (FACT) standards for direct allogeneic live donor care and data reporting requirements. These include submission of direct allogeneic stem cell transplant data to the SCTOD. However, VA considers this part of the comment beyond the scope of the rulemaking as these reporting requirements for bone marrow transplant mainly concern the engraftment and recipient, and not the live donor, and this comment does not pertain to the care and services available to live donors under VA's transplant program.

VA believes that this is more appropriate for internal VA policy than regulation since it concerns internal VA requirements. To the extent that this commenter is suggesting non-VA providers performing bone marrow transplants under VA's transplant program comply with these same data reporting requirements, this is beyond the scope of this rulemaking and would be more appropriate for inclusion in agreements VA enters into with these non-VA providers. VA is making no changes based on this comment.

One commenter stated that OPTN requires that transplant programs only use living donor organs recovered from OPTN approved living donor recovery hospitals and noted that when VA enters into agreements with non-VA facilities for organ transplants, it should ensure that these non-VA facilities are approved for recovery of organs from living donors if the recovery will occur in such facilities. This commenter suggested VA consider clarifying in the final rule the minimum requirements for these non-VA facilities that recover organs from living donors. Relatedly, this commenter recommended the rule be "explicit about requirements for outcomes reporting, compliance monitoring, and other considerations between bone marrow and solid organ transplant, given their distinct contractual relationships with the federal government."

With regards to the comment that VA should ensure that non-VA facilities with which VA enters into agreements for bone marrow or solid organ transplants are approved by OPTN, VA considers this part of the comment beyond the scope of the rulemaking since it does not pertain to the care and services available to live donors under VA's transplant program. The qualifications that VA requires non-VA facilities providing such services to possess is a separate matter that will be addressed by VA in the context of its acquisitions.

In the agreements VA would enter into with non-VA facilities for organ transplants, VA would ensure that the appropriate requirements, such as those requirements for outcomes reporting, compliance monitoring, and other requirements or

considerations, are included in such agreements. This information is commonly set forth in agreements rather than regulations, especially to permit flexibility, as requirements are subject to change. Additionally, the purpose of this rulemaking is to regulate the care and services available to living donors before and after the procedure required in connection with a veteran's transplantation procedure; not to regulate the requirements for reporting, monitoring, or other similar requirements with which non-VA providers must comply.

VA is making no changes based on this comment.

Technical changes not based on comments

VA makes two technical changes not based on comments. Both technical changes are made to 38 CFR 17.395(g), which states the limitations on VA obligations in kidney paired donations. The first change is to replace the term, care, with the term, hospital care, in the introductory paragraph of § 17.395(g). The second change is to replace the term, services, with the term, medical services, in the introductory paragraph of § 17.395(g). These technical changes clarify the specific type of care and services referenced in § 17.395(g) and are consistent with how these terms are used in paragraph (c) of § 17.395. These technical changes will also avoid potential confusion with the terms, non-hospital care and non-medical services, which appear in paragraph (d) of § 17.395.

Based on the rationale set forth in the proposed rule and in this final rule, VA is adopting the proposed rule with changes as noted.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive

impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601-612). VA has determined that this rule will not have a significant impact on a substantial number of small entities because the final rule does not directly regulate or impose costs on small entities and any effects would be indirect. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Assistance Listing

The Assistance Listing numbers and titles for the programs affected by this document are 64.009, Veterans Medical Care Benefits; 64.029, Purchased Care Program; 64.047, VHA Primary Care; 64.042, 64. 045, VHA Ancillary Outpatient Services; 64.042, VHA Inpatient Surgery; 64.040, VHA Inpatient Medicine; 64.041,VHA Outpatient Specialty Care; 64.035, Veterans Transportation Program.

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq*.), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on March 7, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulation Development Coordinator,

Office of Regulation Policy & Management,

Office of General Counsel,

Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 17 as set forth below:

PART 17 – MEDICAL

1. The general authority citation for part 17 continues and an authority citation for §17.395 is added in numerical order to read as follows:

Authority: 38 U.S.C. 501 and as noted in specific sections.

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Section 17.395 is also issued under 38 U.S.C. 1788.

2. Add an undesignated center heading and § 17.395 to read as follows:

HOSPITAL CARE, MEDICAL SERVICES, AND OTHER SERVICES FOR LIVE DONORS

§ 17.395 Transplant procedures with live donors, and related services.

(a) *Scope*. This section provides for medical and non-medical care and services of persons who volunteer to donate a solid organ, part of a solid organ, or bone marrow for transplantation into an eligible veteran transplant candidate, irrespective of a donor's eligibility to receive VA health care for any reason other than to donate a solid organ, part of a solid organ, or bone marrow. It prescribes the type, timing, and duration of hospital care and medical services VA provides, including medical care or services purchased by agreement from a non-VA facility. It also provides for non-medical care and services essential to the prospective live donor's or live donor's participation and for VA reimbursement for that care and services. The section does not provide for eligible veteran transplant candidates' VA medical benefits.

(b) *Definitions*. For purposes of this section:

Initial prospective live donor means an intended recipient's prospective live donor who volunteers to donate a kidney to a recipient other than the intended recipient through kidney paired donation.

Intended recipient means the transplant candidate who VA identifies to receive a live donor's solid organ, part of a solid organ, or bone marrow.

Kidney paired donation means one prospective live donor's voluntary donation of a kidney for transplantation into a recipient other than an intended recipient, paired with the transplantation into the intended recipient of a compatible kidney from a different live donor. Note: For purposes of this section, kidney paired donation includes live donor chains.

Live donor means an individual who is:

(i) Medically suitable for donation;

(ii) Is a compatible match to an identified veteran transplant candidate; and

(iii) Has provided informed consent to undergo elective removal of one solid organ, part of a solid organ, or of bone marrow.

Live donor chain means a set of kidney paired donation matches that begins with a donation of a kidney from a live donor without an intended recipient. Such live donor donates a kidney for transplantation into the intended recipient of a prospective live donor. The prospective live donor then donates a kidney for transplantation into a recipient other than the intended recipient. A chain continues to allow donation and receipt of compatible kidneys.

Live donor follow-up means

(i) For live donors of a solid organ or part of a solid organ, the collection of clinically relevant post-donation live donor data and the provision of recommended clinical laboratory tests and evaluations consistent with Organ Procurement and Transplantation Network policy, and the provision of direct medical care required to

address reasonably foreseeable donor health complications resulting directly from the donation procedure.

(ii) For live donors of bone marrow, the provision of direct medical care required to address reasonably foreseeable donor health complications resulting directly from the donation procedure.

Prospective live donor means a person who has volunteered to donate a solid organ, part of a solid organ, or bone marrow to an intended recipient, and who has agreed to participate in any activity VA deems necessary to carry out the intended recipient's transplant procedure.

Transplant candidate means an enrolled veteran or a veteran otherwise eligible for VA's medical benefits package who VA determines has a medical need for a solid organ, part of a solid organ, or bone marrow transplant.

Transplant recipient means a transplant candidate who has undergone transplantation and received a solid organ, part of a solid organ, or bone marrow from a live donor.

(c) *Hospital care and medical services.* To obtain a solid organ, part of a solid organ, or bone marrow for a VA transplant candidate, VA may provide the following hospital care and medical services to a prospective live donor or live donor:

(1) Before removal of a solid organ, part of a solid organ, or bone marrow, VA will provide examinations, tests, and studies necessary to qualify a prospective live donor to donate a solid organ, part of a solid organ, or bone marrow.

(2) During removal of a solid organ, part of a solid organ, or bone marrow, VA will provide the surgical procedure to remove a solid organ, part of a solid organ, or bone marrow from the living donor whose solid organ, part of a solid organ, or bone marrow will be transplanted into an intended recipient.

(3) After removal of a solid organ or part of a solid organ, VA will provide all hospital care, medical services, and other services which are necessary and appropriate to live donor follow-up as defined in paragraph (b) of this section for a period not less than that which the Organ Procurement and Transplantation Network prescribes or recommends or for a period of 2 years, whichever is greater.

(4) After bone marrow removal, VA will provide direct medical care required to address reasonably foreseeable live donor health complications resulting directly from the bone marrow donation procedure for a period not greater than 2 years.

(5) A prospective live donor who is also a veteran enrolled in VA's health care system may receive care and services authorized in paragraphs (c)(1) and (2) only under this section. A live donor who is also a veteran enrolled in VA's health care system may opt to receive the care and services authorized under paragraph (c)(3) or (4) under either the medical benefits package codified at § 17.38 or under this section, but not both at the same time.

(d) *Non-hospital care and non-medical services.* If VA determines the prospective live donor's or the live donor's presence or proximity is necessary, VA will reimburse the travel costs of the prospective live donor or live donor, including one needed attendant or support person, at the rates provided in § 70.30 of this chapter, without the deductibles required by § 70.31 of this chapter, for:

(1) Travel between the prospective live donor's or live donor's residence and the site of hospital care or medical services authorized in paragraph (c) of this section; and

(2) Temporary lodging:

(i) While the live donor is hospitalized for the organ removal procedure; or

(ii) While the prospective live donor's or live donor's participation in the live donor program requires the prospective live donor's or live donor's presence away from

home at least overnight and the prospective live donor's or live donor's presence or proximity is determined necessary by VA.

(e) *Use of non-VA facilities and non-VA service providers*. (1) If and only if VA and a non-VA facility or non-VA service provider have an agreement governed by 38 U.S.C. 8153 or any other applicable authority in title 38, United States Code, a non-VA facility may provide--

(i) A surgical procedure and care and services described in paragraph (c) of this section; or

(ii) Non-hospital care or non-medical services described and otherwise reimbursable under paragraph (d) of this section.

(2) The prospective live donor or live donor is eligible for hospital care and medical services, or travel services, at a non-VA facility solely for the procedure, care, and services described in paragraphs (c) and (d) of this section as governed by an agreement described in paragraph (e)(1) of this section.

(f) *Participation terminated without completion of the intended recipient's transplantation procedure*. (1) VA will provide the prospective live donor or live donor the care and services described in this section for any VA-authorized participation in the intended recipient's organ or bone marrow transplantation process even if the transplantation procedure for which the prospective live donor or live donor volunteered to donate a solid organ, part of a solid organ, or bone marrow is not completed.

(2) A prospective live donor or a live donor may withdraw his or her informed consent at any time and for any reason. In the case of revocation of consent, VA will pay all the costs authorized under this section for the prospective live donor or live donor up until when the donor revokes consent and ends his or her participation.

(g) *Limitation on VA obligation in kidney paired donations.* In kidney paired donations, VA's obligation to provide any procedure, hospital care, or medical services under this section extends:

(1) To the initial prospective live donor who elects to participate in a kidney paired donation matching program, but only for the examinations, tests, and studies described in paragraph (c)(1) of this section for a prospective live donor before kidney removal.

(2) To the live donor whose kidney the intended recipient will receive or has received but only for the services described in paragraphs (c)(2) and (3) of this section.

[FR Doc. 2022-10764 Filed: 5/31/2022 8:45 am; Publication Date: 6/1/2022]